



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES


Thursday, September 20, 2007


MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. Nos.: 82012-R/ Group I
82012-E/ Group II
82012-G/ Group III
82012-U/ Group IV
82012-L/ Group V

DP Barcode: D342907, D342909, D342910, D342911, D342912

To: Marshall Swindell, PM 33/ Karen Leavy
Regulatory Management Branch
Antimicrobials Division (7510P)

From: Ian Blackwell, Biologist 
Chemistry and Toxicology Team
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Through: Karen Hicks, Team Leader 
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Antimicrobials Division (7510P)

Applicant: Copper Development Association (CDA)

- 1) BACKGROUND: The Copper Development Association requests waivers of the acute toxicity studies for their five new products based upon the composition and form of each product. The products are to be manufactured as doorknobs, doorplates and other solid objects. This waiver proposal is presented in the document:

Antimicrobial Copper Alloys Group I
Toxicology Data Waiver Requests 12/1/2006.
MRID Number 469996-03

- 2) RECOMMENDATIONS: PSB findings are:

- a) The Chemistry and Toxicology Team (CTT) waives the requirements for the acute toxicity studies for these products. CTT consulted Risk Assessment and Science Support Branch (RASSB) toxicologists regarding the issue of the "inert" ingredients found in these five products. These scientists state that there should not be concern regarding any acute toxicity from these products.
- b) This premise (above) that no acute toxicity studies are required for these products is based upon the following assumptions:
 - i) These products will all be marketed or found in the form of **large solid** products such as doorknobs and doorplates. As such, it will be virtually impossible to swallow, inhale or otherwise introduce one of these products into a human body.
 - ii) These products will not be granular, powdered, liquid or suspension in form. Should the physical form of any of these products be, or be changed to, granular, powdered, liquid or suspension, the requirements for acute toxicity studies of the subject product will have to be reevaluated.
- c) One toxicologist did express concern that there may be surface residual materials of concern resulting from the "inerts" that may need to be assessed.

- 3) LABELING:

- a) No precautionary labeling is required.

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Note to PM Team 33:

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The Chemistry and Toxicology Team (CTT) consulted Drs. Steve Malish and Timothy McMahon on these unusual waiver requests.

Ian Blackwell